I

109TH CONGRESS
1ST SESSION

H. R. 870

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2005

Mr. STARK (for himself and Mr. BERRY) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Research and Manufacturers Accountability Act of 2005'' or the ''PhRMA Act of 2005''.

SEC. 2. CONCEALMENT OF SERIOUS ADVERSE DRUG EXPERIENCE.

(a) PENALTY FOR KNOWING CONCEALMENT OF SERIOUS ADVERSE DRUG EXPERIENCE.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) An individual who violates a provision of section 301 shall be imprisoned for a term of a minimum of 20 years and a maximum of life, fined not more than $2,000,000, or both, if—

''(1) the individual is employed as the chief executive officer or a member of the senior executive management group of the manufacturer of a drug; and

''(2) the violation involves, with respect to such drug, knowing concealment by the individual of evidence of a serious adverse drug experience (as that term is defined in section 505(o)).''.

(b) ANNUAL ATTESTATION BY CEO REGARDING ANY SERIOUS ADVERSE DRUG EXPERIENCE.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 505 (21 U.S.C. 355), by adding at the end the following:

''(o) ANNUAL ATTESTATION BY CEO REGARDING ANY SERIOUS ADVERSE DRUG EXPERIENCE.—

''(1) REQUIREMENT.—For each drug for which an approval of an application filed under subsection (b) or (j) is in effect, the Secretary shall require the chief executive officer of the manufacturer of the drug to submit a separate, written attestation on an annual basis—

''(A) stating that the manufacturer has disclosed to the Secretary all evidence of any serious adverse drug experience related to the drug; and

''(B) describing the process by which the manufacturer ensures that such disclosure has occurred.

''(2) DEFINITIONS.—For purposes of this subsection:

''(A) The term 'evidence of any serious adverse drug experience' includes any evidence of a serious adverse drug experience that—

''(i) is obtained by the manufacturer involved from any source of information, foreign or domestic, including any information obtained from a clinical trial conducted before or after approval of the drug, from postmarketing surveillance of

the drug, or from a postmarketing report by a physician; or

''(ii) is required by any provision of this Act to be reported by the manufacturer to the Secretary.

''(B) The term 'serious adverse drug experience' means an adverse drug experience occurring at any dose that results in—

''(i) death, a life-threatening adverse drug experience, inpatient hospitalization, prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or

''(ii) a medical event that, based on appropriate medical judgment, may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in clause (i).

''(3) INITIAL ATTESTATION.—The Secretary shall require that the first attestation under this subsection for a drug be submitted—

''(A) in the case of a drug for which approval of an application filed under subsection

(b) or (j) is in effect on the date of the enactment of this subsection, not later than 1 year after such date; and

"(B) in the case of any other drug, not later than 1 year after the the date of such approval for the drug.

"(4) FAILURE TO SUBMIT.—If the chief executive officer of a manufacturer of a drug for which an approval of an application filed under subsection (b) or (j) is in effect fails to submit a timely attestation for the drug as required by paragraph (1), the Secretary—

"(A) may issue an order withdrawing approval of the application; and

"(B) shall not revoke such an order, or otherwise approve or reinstate the application, unless—

"(i) the Secretary conducts a review of the drug's safety;

"(ii) the Secretary determines that the drug is safe for use; and

"(iii) the manufacturer reimburses the Secretary for the costs of such review and determination.

''(5) SUPPLEMENTAL INFORMATION.—In conducting a review under paragraph (4)(B)(i), the Secretary may require the manufacturer of the drug involved to submit supplemental information on the drug's safety.'';

(2) in section 301 (21 U.S.C. 331), by inserting at the end the following:

''(hh) The failure to submit an attestation in accordance with section 505(o).''; and

(3) in section 303 (21 U.S.C. 333), as amended by subsection (a), by adding at the end the following:

''(i)(1) A person who violates section 301(hh) by failing to submit an attestation in accordance with section 505(o) shall be fined—

''(A) in the case of an individual, in accordance with title 18, United States Code; and

''(B) in the case of any other person, not more than $1,000,000.

''(2) Each 30-day period during which such violation continues shall constitute a separate offense.''.

(c) DEADLINE FOR POSTMARKETING STUDIES.—

(1) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) in section 505 (21 U.S.C. 355), as amended by subsection (b)(1), by adding at the end the following:

''(p) DEADLINE FOR POSTMARKETING STUDIES OF DRUGS.—

''(1) REQUIREMENT.—If the Secretary requires the manufacturer or sponsor of a drug to conduct a postmaketing study of the drug, the Secretary shall require the manufacturer or sponsor to complete the study by a specified deadline.

''(2) EXTENSION.—On request, the Secretary may extend a deadline established under this subsection.'';

(B) in section 301 (21 U.S.C. 331), as amended by subsection (b)(2), by inserting at the end the following:

''(ii) The failure to complete a postmarketing study by the deadline established by the Secretary for such study under section 505(p).''; and

(C) in section 303 (21 U.S.C. 333), as amended by subsections (a) and (b)(3), by adding at the end the following:

''(j) A person who violates section 301(ii) by failing to complete a postmarketing study for a drug by the deadline established by the Secretary for such study under sec-

tion 505(p) shall be fined not more than $5,000,000. Each 30-day period during which such violation continues shall constitute a separate offense.''.

(2) APPLICATION.—The amendments made by this subsection apply only with respect to a drug for which an application is filed under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 33) on or after the date of the enactment of this Act.

(d) PROHIBITION AGAINST INDEMNIFICATION.—No person shall indemnify the chief executive officer of a drug manufacturer or any other individual for any fine incurred under the amendments made by this Act.

○